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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

(Sacramento)

GENOMIC HEALTH, INC.,

Plaintiff and Appellant,

v.

SANDRA SHEWRY, as Director, etc.,

Defendant and Respondent.

C061688

(Super. Ct. No.
34-2008-00010215-CU-
WM-GDS)

Genomic Health, Inc. (Genomic Health) filed a petition for writ of mandate against the Department of Health Care Services (the Department), seeking a declaration that the Department was required to pay Genomic Health for services rendered to Medi-Cal patients before June 1, 2007. The trial court denied the petition because Genomic Health had failed to exhaust administrative remedies.

On appeal, Genomic Health contends that the trial court erred because it would have been futile to exhaust administrative remedies. We conclude that Genomic Health's

contention is without merit because the record does not support its assertion that exhaustion of administrative remedies would have been futile.

BACKGROUND

Medi-Cal "represents California's implementation of the federal Medicaid program" (*Robert F. Kennedy Medical Center v. Belshé* (1996) 13 Cal.4th 748, 751.) Medi-Cal is administered by the Department with Electronic Data Systems (EDS) acting as a fiscal intermediary to process claims by providers.

The California Code of Regulations allows providers of medical services under Medi-Cal to file an appeal with EDS if the claim is denied. (Cal. Code Regs., tit. 22, § 51015, subd. (a); see also Welf. & Inst. Code, § 14104.5 [enabling statute].) EDS reviews the merits and provides a written decision. (Cal. Code Regs., tit. 22, § 51015, subd. (c).) If the provider is not satisfied with EDS's decision, the provider may seek appropriate judicial remedies. (Cal. Code Regs., tit. 22, § 51015, subd. (d).)

Genomic Health is a laboratory that provides specialized genetic testing, called Oncotype Dx, to assist in the management of breast cancer treatment. In April 2006, it became an authorized Medi-Cal provider of services. The same month, Genomic Health began providing laboratory services on behalf of Medi-Cal recipients. Those services were billed to Medi-Cal as unspecified clinical laboratory tests using Medi-Cal code number 84999. Genomic Health's claims for services rendered before

June 1, 2007, were denied because of various billing errors, and Genomic Health failed to file an appeal pursuant to section 51015 of title 22 of the California Code of Regulations concerning any of the rejected claims.

At some time on or after June 1, 2007, the Department established a code number specifically for the Oncotype Dx testing -- code number S3854. In December 2007, the Department provided an update concerning the use of code number S3854 in Bulletin 402. The bulletin listed the requirements to be met before a claim submitted using code number S3854 could be approved for payment and it made the requirements retroactive to June 1, 2007. The bulletin concluded: "Providers who previously billed . . . code S3854 for dates of service on or after June 1, 2007, may have had their claims denied because the procedure was not yet a Medi-Cal benefit. To be reimbursed, providers may re-submit the denied claims"

In May 2008, Genomic Health filed this action seeking a writ of mandate "requiring [the Department] to cover Oncotype Dx services furnished by Genomic Health to Medi-Cal patients between April 20, 2006, and June 1, 2007, based on the same criteria and at the same payment rate applicable to Oncotype Dx services rendered on or after June 1, 2007."

The Department demurred to the petition, arguing that Genomic Health did not exhaust its administrative remedies, and the trial court sustained the demurrer with leave to amend.

Genomic Health filed a first amended petition, and the Department again demurred based on failure to exhaust

administrative remedies. The trial court overruled the demurrer but again considered the issue after the Department filed an answer to the petition.

On the issue of exhaustion of administrative remedies, Genomic Health conceded that it had not used the administrative appeal procedure pursuant to section 51015 of title 22 of the California Code of Regulations concerning any of the rejected claims. Instead, it claimed that to file such an appeal would have been futile because the Department's policy, as reflected in Bulletin 402, was to pay only for services provided on or after June 1, 2007.

In support of its futility argument, Genomic Health submitted two documents. The first was the Department's Bulletin 402. And the second was a series of e-mails exchanged between Genomic Health and various individuals within the Department. The e-mails show that Genomic Health inquired about resolving the denial of the claims for services rendered before June 1, 2007; however, they do not show whether those claims would not have been paid if Genomic Health had filed an administrative appeal.

The Department submitted a declaration of Debra Garrick, who is a senior insurance analyst with EDS. She researched the claims filed by Genomic Health for services rendered before June 1, 2007, and stated: "I searched EDS'[s] database to determine whether Genomic presented claims of these individuals for reimbursement. In most instances, I found that Genomic had presented such claims, and some multiple times. The code used

by Genomic with respect to most of these claims was #84999. This code number is significant because it designates the services provided as 'clinical laboratory tests.' The code used at the time was fully reimbursable by Medi-Cal assuming that the claims were properly presented in form and content to EDS by Genomic. The database indicated that the claims presented by Genomic for the individuals . . . with the dates of service noted were all denied because of a variety of Genomic billing errors." (Underscoring in original.)

Garrick noted that Genomic Health did not use the formal appeal process to challenge the denials with respect to services billed under code 84999.

Garrick's declaration continued: "In December 2007, Medi-Cal Bulletin 402 indicated that [the Department] would reconsider payment for denied claims billed to [EDS] with service code #S3854 for dates of service on or after June 1, 2007. The providers were instructed to rebill the affected claims. For the most part, Genomic billed claims with service code #84999 with a date of service range between April 13, 2006 and May 29, 2007. This code and dates of services range was outside the defined parameter." (Fn. omitted.)

The trial court found that Genomic Health had not met its burden of showing that it would have been futile to file an administrative appeal. Although the trial court was of the opinion that the statement in Garrick's declaration concerning the code and dates of service being "outside the defined parameter" was ambiguous, it concluded that that statement "does

not establish that claims for Oncotype Dx services billed prior to June 1, 2007 would never be paid." "On the contrary," the court continued, "the Garrick declaration indicates that claims for these services were previously submitted under a different service code, #84999, which code was fully reimbursable, but that the claims were denied because of a variety of billing errors." The court therefore denied the petition for writ of mandate.

DISCUSSION

I

Exhaustion of Administrative Remedies

There is no dispute that Genomic Health did not exhaust administrative remedies. As Garrick noted, Genomic Health did not use the formal appeal process after the billings for services rendered before June 1, 2007, were denied. Instead, Genomic Health claims that pursuing administrative remedies was futile because EDS could not grant the claims for services before June 1, 2007. We conclude that the record does not support Genomic Health's assertion of futility.

A. *Exhaustion and Futility*

Section 1094.5 of the Code of Civil Procedure provides for judicial review of *final* administrative proceedings. Because the administrative proceedings must be final, the failure to exhaust administrative remedies prevents a party seeking a writ of mandate from obtaining relief in the courts. (*Unnamed Physician v. Board of Trustees* (2001) 93 Cal.App.4th 607, 619.) "[T]he rule is that where an administrative remedy is provided

by statute, relief must be sought from the administrative body and this remedy exhausted before the courts will act."

(*Abelleira v. District Court of Appeal* (1941) 17 Cal.2d 280, 292.) This requirement is jurisdictional. (*Id.* at p. 293.)

There are, however, exceptions to the exhaustion doctrine. "The doctrine is inapplicable where 'the administrative remedy is inadequate [citation]; where it is unavailable [citation]; or where it would be futile to pursue such remedy [citation].'" (*Automotive Management Group, Inc. v. New Motor Vehicle Bd.* (1993) 20 Cal.App.4th 1002, 1015.)

"The petitioner bears the burden of demonstrating that the issues raised in the judicial proceeding were first raised at the administrative level. [Citation.]' [Citation.] An appellate court employs a de novo standard of review when determining whether the exhaustion of administrative remedies doctrine applies. [Citation.]" (*Sierra Club v. City of Orange* (2008) 163 Cal.App.4th 523, 536.)

"The futility exception requires that the party invoking the exception 'can positively state that the [agency] has declared what its ruling will be on a particular case.' [Citation.]" (*Jonathan Neil & Assoc., Inc. v. Jones* (2004) 33 Cal.4th 917, 936, brackets in original.)

B. *Analysis of Record*

Genomic Health argues that the record shows that pursuing the administrative appeal process would have been futile. In making this argument, Genomic Health asserts that three proven "facts" establish the futility: in Genomic Health's words,

"(1) [Genomic Health's] repeated unsuccessful requests on [the Department] to cover Oncotype Dx services furnished between April 20, 2006 and June 1, 2007; (2) the grievance process of Section 51015 is administered by the Medi-Cal fiscal intermediary, EDS, which is contractually bound to follow [Department] policy regarding the effective date of services covered by Medi-Cal; and (3) the fact that the policy set forth in the December 2007 Medi-Cal bulletin [Bulletin 402] only allows a provider to resubmit to [EDS] for reprocessing of payments claims for Oncotype Dx services furnished on or after June 1, 2007 for which payment had been previously denied." These "facts" fail to establish futility, either individually or collectively.

1. Repeated Requests to Cover Services

In support of its argument that exhaustion of administrative remedies was futile, Genomic Health filed hard copies of several e-mails that counsel for Genomic Health sent to various Department personnel trying to "resolve" the issue of whether Genomic Health would be paid for services rendered before June 1, 2007. Counsel never received a substantive response. The only response reflected in the filed e-mails is a statement by counsel for Genomic Health which he attributed to a Department employee stating: "[O]rdinarily a provider is furnishing services at its own risk when it furnishes a newly covered service prior to the effective date of the coverage." This statement, however, does not establish that the Department

had a policy of prohibiting payment of claims for services rendered by Genomic Health before June 1, 2007.

In any event, e-mails to Department personnel do not constitute the remedies contemplated by the exhaustion of remedies requirement. Instead, the remedies are those provided by statute -- here, the administrative appeals process pursuant to section 51015 of title 22 of the California Code of Regulations, as authorized by Welfare and Institutions Code section 14104.5. Therefore, Genomic Health's e-mail requests for clarification of the Department's policy did not excuse exhaustion of administrative remedies.

2. EDS as Bound by Department Policy

In the course of this litigation, Genomic Health contended, and the Department conceded, that EDS is bound by Department policy in administering Medi-Cal claims. From this major premise, Genomic Health argues that EDS was bound to follow the Department's policy prohibiting payment of claims for services rendered by Genomic Health before June 1, 2007. The problem with this logic is that Genomic Health has failed to establish the minor premise that the Department has a policy prohibiting payment of claims for services rendered by Genomic Health before June 1, 2007.

Genomic Health argues that it is not challenging the nonpayment of any particular claim. Instead, Genomic Health seeks to challenge the policy in Bulletin 402 setting the date of June 1, 2007, for retroactive claims using code number S3854. According to Genomic Health, because of Bulletin 402, EDS does

not have authority to pay claims for services rendered before June 1, 2007.

This argument suffers from two problems. First, Genomic Health offers no authority except its own opinion that Bulletin 402 precludes payment for services rendered before June 1, 2007. On its face, the bulletin does not even apply to those claims. It applies to claims for services rendered "on or after June 1, 2007." And second, the Garrick declaration states that the code number used by Genomic Health in seeking payment for services rendered before June 1, 2007 (code number 84999) "was fully reimbursable by Medi-Cal assuming that the claims were properly presented in form and content to EDS by Genomic." (Underscoring in original.)

Perhaps perceiving this deficiency in establishing what the Department's policy is, Genomic Health claims that language found later in the Garrick declaration supports its premise that there is such a policy. Referring to Bulletin 402, Garrick stated: "For the most part, Genomic billed claims with service code #84999 with a date of service range between April 13, 2006 and May 29, 2007. This code and dates of service range was outside the defined parameter." Citing this language, Genomic Health argues: "Since they [apparently, the code and dates of service] were outside the 'defined parameter' of the Bulletin, [EDS], who is contractually bound to abide by Medi-Cal rules [record citation], including Medi-Cal bulletins, could not have covered and paid for such services. [The Department] is being

disingenuous in suggesting any other conclusion regarding such pre-June 1, 2007 services."

This argument fails because, as we have noted, Bulletin 402 does not apply to claims for services rendered before June 1, 2007. In fact, that is precisely consistent with Garrick's statement that the code (number 84999) and the dates of service (before June 1, 2007) are outside the parameters of Bulletin 402, which applies to code number S3854 and dates of service on or after June 1, 2007.

Therefore, Genomic Health has failed to establish that the Department has a policy that prohibits payment for Genomic Health services rendered before June 1, 2007. At best, Genomic Health has shown that the Department's policy authorized payment for services billed using code number S3854 only if those services were rendered after June 1, 2007. But that does not negate the possibility that EDS could have paid for those services billed under code number 84999. If there is such a policy, Genomic Health has failed to establish that fact on the record.

Simply, if Genomic Health had pursued its administrative remedies and pressed its claim that the Department was required to reimburse Genomic Health for services rendered before June 1, 2007, we would know what the Department's policy is with respect to this issue, as implemented by EDS. Therefore, this case shows the importance of exhausting administrative remedies, not the futility of doing so.

3. Bulletin 402

Because Bulletin 402 does not apply to claims for services rendered before June 1, 2007, we need not discuss further what Bulletin 402 allows and prohibits. Genomic Health's assertion that Bulletin 402 establishes futility of exhausting administrative remedies is without merit.

C. *No Futility Shown*

Genomic Health has failed to bear its burden of establishing on the record that exhaustion of administrative remedies was futile. The cases that Genomic Health cites are consistent with this conclusion because, unlike this case, there was in each of the cases cited an identifiable policy or regulation being challenged.

For example, in *County of Sacramento v. Lackner* (1979) 97 Cal.App.3d 576, this court concluded that counties could pursue their action for damages against the state because the state had invalidly adopted an emergency regulation to limit Medi-Cal payments to the counties. The court found that the judicial remedy of traditional mandate was appropriate because the counties sought disbursement of Medi-Cal payments as provided by statute. (*Id.* at pp. 581-582, 587-588.)

While Genomic Health has asserted that a policy of prohibiting payment of claims for services rendered by Genomic Health before June 1, 2007, is inconsistent with federal regulations, Genomic Health has failed to establish that such prohibition was the Department's policy. Therefore, *County of Sacramento v. Lackner* is unhelpful. (See also *Union of American*

Physicians & Dentists v. Kizer (1990) 223 Cal.App.3d 490, 502-503 [not requiring exhaustion of administrative remedies when challenged regulations that would have been applied in administrative review were not lawfully adopted]; *Venice Town Council, Inc. v. City of Los Angeles* (1996) 47 Cal.App.4th 1547, 1567-1568 [not requiring exhaustion of administrative remedies when challenging city's overarching policies].)

Genomic Health bore the burden of establishing that it would have been futile to exhaust administrative remedies. Because Genomic Health did not bear that burden, the trial court properly entered judgment in favor of the Department.

II

Validity of Department Policy

Having argued that an administrative appeal would have been futile and therefore it was unnecessary to exhaust administrative remedies, Genomic Health contends that we should order issuance of the writ because the Department's policy of prohibiting payment for services rendered by Genomic Health before June 1, 2007, is inconsistent with federal requirements. We reject this contention for two reasons already discussed: first, it was necessary to exhaust administrative remedies and, second, Genomic Health has failed to establish the existence of such a policy.

DISPOSITION

The judgment is affirmed. The Department is awarded its costs on appeal. (Cal. Rules of Court, rule 8.278(a)(2).)

NICHOLSON, Acting P. J.

We concur:

RAYE, J.

HULL, J.